Final Report of the Advisory Panel on Natural Health Products

Regulatory Framework for Natural Health Products

May 13, 1998

Health Canada Santé Canada

The attached report has been independently prepared by the Advisory Panel on Natural Health Products and provides advice to the Therapeutic Products Programme and to the House of Commons Standing Committee on Health on the regulation of Natural Health Products in Canada. This is the Panel's "Final Report" as presented to the Standing Committee on May 13, 1998. Additional information on the Panel, its meetings and Interim Report, may also be found on this website.

May 13, 1998

104-07357/

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Executive Summary

After a year of reflection and deliberation, the Advisory Panel on Natural Health Products has proposed a regulatory framework for natural health products (NHPs) in Canada. The principal objective of the framework is to ensure that consumers have freedom of choice and access to products that are safe and of high quality, and that claimed benefits are supported by reasonable evidence.

At present, there is no comprehensive regulatory or policy framework within Health Canada for the regulation of NHPs. However, the Panel considered all natural health products, including conventional foods, supplements, functional foods, and other therapeutic products, in the development of a suitable new framework to regulate NHPs.

While the Panel has developed a framework that could apply to other therapeutic categories, the Panel focused upon products in dosage form and marketed as natural health products for human use. This framework describes a mechanism to meet growing consumer demand for products that allow consumers to take greater responsibility for their own health. At the same time, however, the proposed regulatory process seeks to protect the Canadian public from unsafe products and fraudulent claims of health benefits.

To achieve this critical balance, the Advisory Panel recommends fundamental changes to both the *Food and Drugs Act* and the regulatory administrative system.

Key to these changes is the recognition that many existing regulatory controls for pharmaceuticals are too stringent and cumbersome for NHPs, while regulations for foods are inadequate. Thus, the Panel calls for a new regulatory category for NHPs, separate and distinct from both foods and pharmaceuticals. Within that category, NHPs would be regulated in ways that reflect their unique characteristics.

In particular, the Advisory Panel report calls for an effective, transparent and cost-efficient process to license NHPs. This process, a combination of pre-market assessments and post-market notifications, would permit speedy access to market for products that are safe, of high quality and have claims supported by reasonable evidence..

The proposed regulatory framework would be staffed by individuals sensitive to the unique nature of NHPs and the philosophies underlying their use. Administrative decisions would be based on product evaluations carried out by practitioners and other specialists highly skilled in the field of natural remedies. The regulatory framework would also include an open and transparent appeals mechanism.

This regulatory process would reflect the Advisory Panel's strongly held belief that the overwhelming majority of NHPs are inherently safe, and that risks, where they exist, can be managed to acceptable levels. This framework considers dosage forms, claims and the relative safety of the products as its cornerstones. Thus, the chief risk-management tools built into the proposed regulatory framework are product labelling, and provisions to restrict access to certain products without the intervention of experienced health practitioners.

The Panel concluded that under the proposed framework, NHPs would be permitted to make structure/function, risk-reduction and therapeutic claims, provided recognized clinical, traditional or culturally-based evidence supported such claims. There was vigorous disagreement over whether products should be required to carry claims; a clear majority, however, felt there are sufficient and compelling reasons to permit the marketing of claim-free products. Any natural health product marketed without claims would be required to meet the same safety and quality requirements as those products making claims and should carry a label advisory that the effectiveness of the product had not been evaluated by Health Canada.

The Panel also agreed that the regulatory framework for NHPs would be meaningless without the immediate rescindment of Schedule A of the *Food and Drugs Act*. The Schedule lists medical conditions for which treatments, preventatives or cures cannot be sold or advertised to the Canadian public. The Panel believes the Schedule poses unnecessary and burdensome restrictions on consumer use of NHPs.

Finally, the Panel recommends that, not unlike the principles underlying holistic medicine and complementary health care, the proposed new regulatory framework be considered in its entirety. When enacted, moreover, it should regularly be reviewed with an eye to ensuring it continues to meet its objective of facilitating reasonable and informed public access to safe, high quality natural health products.

1. Background

As part of a growing appreciation for the role that lifestyle choices play in human well-being and disease prevention, Canadians are becoming increasingly willing to shoulder more responsibility for their own health. With this trend has come a new awareness of health products and practices profoundly different from the conventional Western medical and pharmaceutical model.

Indeed, therapies and remedies derived from ancient sources of knowledge – including European, Chinese, East Indian and Aboriginal – have found enormous appeal in contemporary Canadian society. Canadians of all ages and all walks of life are anxious to explore herbs and other natural-source products as a means to take greater control over their own health care.

Consumer access to such products has been limited because existing law is inadequate for the regulation of Natural Health Products (NHPs).

Insofar as NHPs are controlled at all, they tend to fall – essentially by default – under the federal *Food and Drugs Act*. However, the Panel felt that the definitions for neither foods nor drugs properly describe NHPs. Consequently, the Panel recommends a restructuring of concepts to specifically address natural health products (which are neither foods nor drugs) and drugs. This has meant that with the emergence of the popularity of NHPs with Canadians, the regulatory framework currently affecting these products needs substantive revision to meet the unique needs of natural-source products.

The effect of the excessively stringent regulations is that product approval for marketing is expensive and slow -- if attainable at all. This places NHP vendors at a disadvantage in the competitive North American market. Consequently, products are often sold without adequate labelling information, smuggled into a black or gray market, or not sold at all.

The mandate of the Advisory Panel on Natural Health Products was to explore the issues surrounding the regulation of natural health products, and to develop a revised policy and regulatory framework. In particular, the Panel was invited to consider the balance between freedom of choice and access for consumers, and the need for government intervention to protect public health.

The result of these deliberations is the proposed regulatory framework described in this report. The framework was crafted to ensure that government regulation, guided by accomplished specialists in the field of natural health remedies, will enable consumers to enjoy free choice and ready and informed access to safe, effective, high-quality products.

1.1 The Advisory Panel

In response to public concern about the regulation and accessibility of natural health products, the former federal health minister, the Hon. David Dingwall, directed the Therapeutic Products Program (TPP) of Health Canada to establish an advisory panel to examine and suggest improvements to the policies and regulations governing these substances.

Constituted initially as the Advisory Panel on Herbal Remedies in May 1997, the Panel's mandate was expanded in October 1997 upon the request of the Panel to include "traditional herbal medicines; traditional Chinese, Ayurvedic (East Indian) and Native North American medicine; homeopathic preparations; and vitamin and mineral supplements." With its name changed to the Advisory Panel on Natural Health Products, the list of products that fall under the definition of NHPs was expanded further by the Panel.

The Hon. Allan Rock, Mr. Dingwall's successor, also requested that "once it has completed its recommendations, the Advisory Panel appear before the House of Commons Standing Committee on Health." The Committee was conducting a public review of NHPs during the fall of 1997 and the spring of 1998.

Chaired by Dr. Frank Chandler, director of the College of Pharmacy at Dalhousie University in Halifax, the 18-member Panel comprised a broad cross-section of stakeholders, including consumer groups, growers, retailers, exporters and importers, manufacturers, practitioners of traditional and orthodox forms of medicine, and pharmacists.

The Panel met six times in facilitated workshop sessions. TPP staff, including the Director General, were present to provide background information and to respond to questions from the Panel. TPP staff also served as secretariat to the Panel. The last meeting in April 1998 was conducted with only one TPP staff member present.

A facilitated website conference centre was used in preparing an early draft of an interim report. This interim report was presented to the House of Commons Standing Committee on Health in February 1998.

At the request of the Minister of Health, an independent journalist served as recorder and drafter of the final report. The present report marks the completion of the Panel's mandate.

1.2 Guiding Principles

The Advisory Panel developed and applied the following principles to guide the formulation of recommendations for a new regulatory framework for natural health products. The proposed framework must:

- recognize the nature of natural health products.
- ensure consumers have freedom of choice of products which are safe, of high quality and that claimed benefits are supported by reasonable evidence.
- ensure that sufficient and valid product information is available for consumers to make safe and informed decisions.
- recognize the need for a regulatory body with decision-making power, expertise and experience with natural health products and which is generally acceptable to both the natural health products sector and government.
- recognize the various culturally-based complementary medicine models and allow for the existence of traditional and culturally-based medical paradigms.
- provide for an effective and cost-efficient system of compliance to regulations.
- ensure competitors are treated fairly and equitably.
- provide regulations that do not place inappropriate cost or other burdens on manufacturers/importers/distributors and consumers of products and thereby ensure access to a wide range of affordable products.
- recognize the need for an open and transparent process of appeals, to an appropriate body.

2. Natural Health Products

Insofar as NHPs are controlled at all, they tend to fall – essentially by default – under the federal *Food and Drugs Act*. However, the Panel felt that the definitions for neither foods nor drugs properly describe NHPs. Consequently, the Panel recommends a restructuring of concepts to specifically address natural health products (which are neither foods nor drugs) and drugs.

NHPs are defined by the Panel as "substances or combinations of substances

Food

Under the *Food and Drugs Act*, a "food" is defined as "any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever."

consisting of molecules and elements found in nature, and homeopathic preparations, sold in dosage form for the purpose of maintaining or improving health and treating or preventing diseases/conditions." Examples include, but are not limited to, homeopathic preparations, vitamins, minerals, enzymes, co-enzymes, co-factors, herbs or botanicals, animal source substances, and a variety of molecules extracted from natural substances such as amino acids, polysaccharides, peptides, naturally occurring hormones and precursors as well as naturally occurring molecules synthesized by chemical or biological means.

2.1 Therapeutic Products in Dosage Form

Because the existing definitions do not satisfactorily capture the meaning of natural health products, including their fundamental value in maintaining a state of well-being, the Advisory Panel recommends the following linked changes:

Drugs

Under the *Food and Drugs Act*, "drug" includes "any substance or mixture of substances manufactured, sold or represented for use in

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
- restoring, correcting or modifying organic functions in human beings or animals, or
- disinfection in premises in which food is manufactured, prepared or kept."

- The category of "Drugs" in the *Food and Drugs Act* would be replaced by the term **Therapeutic Products in Dosage Form.** Dosage forms would include but not be limited to capsules, tablets, injectable substances, oral solutions, topical preparations (such as liquids, creams, ointments and patches), suppositories and inhalants.

- The definition of **Therapeutic Products in Dosage Form** would be expanded to incorporate the intended use of the products in the maintenance of wellness.

- The Therapeutic Products in Dosage Form section would be divided into two categories, entitled **Pharmaceuticals** and **Natural Health Products**

- **Pharmaceuticals** would continue to include some products now defined as drugs, including pharmaceutical medications, biologics and radiopharmaceuticals, and conventional medical devices.

- **Natural Health Products** would then encompass "Substances or combinations of substances consisting of molecules and elements found in nature, and homeopathic

preparations, sold in dosage form for the purpose of maintaining or improving health and treating or preventing diseases/conditions."

The Panel also recognized the emergence of devices which may also fit the principles of Natural Health Products but did not reach a conclusion on a clear definition. The Panel was of the opinion that medical devices should be regulated according to the same principles of risk management and standards of evidence recommended in this framework.

2.2 Scope of the Definition

The Advisory Panel notes that the above changes would allow for a new regulatory framework to govern all naturally occurring molecules and elements and homeopathic preparations sold in dosage form in Canada. Several consequences flow from this definition:

- All products sold in dosage form, including nutraceuticals, whether produced domestically or imported, are covered by the definition.
- Functional foods and substances sold in bulk, such as herbs used by practitioners of Traditional Chinese Medicine, are not covered because they are not marketed in dosage form.
- Products cultivated or imported for personal use are excluded from the definition, which is confined to products that are available commercially. For example, herbs used by Aboriginal spiritual leaders in a religious context would not be subject to regulation. The Panel did not wish to interfere with the legitimate access by patients, through their practitioners, to products not readily available in Canada.
- The definition applies only to products in dosage form marketed for use in human health care.

3. The Challenge

The Advisory Panel was cognizant of a number of imperatives that needed to be respected and addressed simultaneously by any new regulatory framework for natural health products. Where several potentially conflicting interests were apparent, they needed to be brought into harmony.

And yet, the Panel believed strongly that the mission can be accomplished -- that it is desirable and possible to devise a system with the appropriate intent, processes and safeguards necessary to serve the public interest.

This section describes some of the philosophical considerations that shaped the Panel's

final recommendations:

➢ **Regulations of natural health products must respect their unique character**.

Unlike synthetic medications, substances found in nature often have a long tradition of use; with experience, substantial bodies of knowledge have tended to form around many NHPs. This means that regulatory assessments of NHPs must rely on forms and sources of supporting evidence that may differ substantially from those required for pharmaceutical evaluations.

Similarly, the vast majority of natural-source products are inherently safe and should therefore be permitted on the market with a minimum of regulatory delay. The risks of using products that -- for reasons of toxicology or potential misuse -- may be less safe can often be mitigated by appropriate labelling or the intervention of a professional.

➢ **Regulatory controls must not unduly restrict the consumer's free access to and choice of safe, effective and clearly labelled natural health products.**

The Panel strongly upheld the principle of consumer choice. For that reason, the regulatory framework was crafted to permit the maximum number of quality products onto Canadian shelves in the shortest reasonable period of time.

At the same time, however, panel members felt that free choice could only be exercised once certain baseline assumptions had been met.

First and foremost, the public needs to be able to presume that products were cultivated, manufactured or otherwise handled according to certain minimum standards of good manufacturing practice. Thus, the consumer must be confident that a product is, in fact, what the package label claims it is, and that it was produced in clean premises according to properly established processes.

Second, consumers have expressed a strong interest in products with claimed health benefits. They need to be assured that the products will do what it claims to do.

Third, consumer choice must be informed. Regulations must therefore ensure that the NHP industry sells its products with meaningful labels, product inserts, professional direction or other means of communicating with the buying public. Usage information must include all the applications, cautions, restrictions or other messages necessary to enable genuinely informed consumer choice.

➢ **Regulatory costs must be contained**

Clearly, consumer choice is influenced by product pricing. Many Canadians choose NHPs imported from the United States or elsewhere that, even if their quality is not assured, can be purchased at a lower price.

The Panel felt strongly that the Canadian public interest would be best served by making safe, high-quality products readily available at prices that consumers would deem reasonable and competitive.

Thus, a new regulatory framework must operate in a manner that does not add undue cost to the marketing of Canadian products. Cost containment is a function of product assessments and market entry procedures that are not excessively protracted, burdensome or complicated. In short, assessments must be in reasonable proportion to risk which, in the case of NHPs, is generally low.

4. Objective

In light of the foregoing principles, the objective of the proposed regulatory framework for natural health products may be summarized as follows:

To give Canadian consumers reasonable and informed access to, and free choice of, safe, high-quality natural health products, and to ensure that claimed benefits are supported by reasonable evidence.

5. The Regulatory Framework -- An Overview

The Advisory Panel felt strongly that federal government regulation of NHPs should be permissive rather than the prescriptive, its interventions minimalist unless potential risks to the public warrant greater intrusion by the state. The administration of this regulatory framework should be guided by the expertise of individuals skilled in the field of natural health care. The regulator must be thoroughly independent of other interests and influences, particularly other administrative regulatory bodies within Health Canada. In that context, a proposed structure for the regulatory authority is discussed in Section 6 of this report.

Under the proposed regulatory framework, all natural health products sold in or into Canada would be required to meet specified criteria for safety and quality. The issues surrounding these criteria are discussed in Section 7.

In addition to meeting safety and quality requirements, NHPs may be permitted to carry claims of health benefits. Where such claims are made, they may be taken into account in the product assessment by regulators. For details on the health-claims issue, please refer to Section 8.

Finally, the proposed framework is effectively based on a risk-management model. This would identify and reduce hazards to the Canadian public, while permitting the speedy marketing of demonstrably safe, effective and high-quality products. Sections 9 through 11 summarize the

mechanisms and tools that would allow the regulatory authority to function according to this model.

The regulatory authority would manage NHPs on two levels. Certain products would be eligible for marketing with only a post-market notification to the regulatory authority. The remainder would be subject to pre-market regulatory assessments. The distinction between the two levels, and the standards of evidence to be used in product assessments, are detailed in Section 11.

6. The Regulatory Authority

Current regulatory processes for pharmaceuticals are largely inappropriate for natural health products: they amount to regulatory overkill.

Conversely, regulation under the Foods Directorate is inadequate for NHPs. For one thing, manufacturing and quality standards are voluntary, and there are no requirements for product review or approval. Moreover, under current law, manufacturers and vendors of foods are not permitted to make claims of health benefits for their products.

Thus, NHPs require a separate regulatory category and framework that reflects their unique characteristics, while ensuring that consumers are fully informed about the product. To carry out this mandate, a separate regulatory administration, specific to NHPs is therefore essential.

While the Panel agreed that the regulatory administration should be distinct and separate from the administrative structures currently operating in either the food sector or pharmaceutical sectors, there was no consensus on the structure that could achieve this objective. Some held out for a separate body, akin to a federal agency. Others felt the key aims could be met by a separate regulatory body within Health Canada. Others still held that responsibility for NHPs could lie within TPP.

However, the Panel insisted that the organization be managed and staffed by people demonstrating a deep-seated understanding of natural health products and their uses. It was proposed that in evaluating and regulating NHP products, a skeleton group of administrators seek counsel from appropriate working groups of natural health practitioners and others active in the NHP industry. In the case of new products, or new uses for existing products, the working groups could, in turn, solicit the advice of other experts in relevant fields such as traditional Chinese medicine or homeopathy.

The Panel recommends that expert groups advise the Minister on the scientific or evidential validity of product submissions. To that end, the Panel believes that administrative personnel should not ordinarily be in a position to overturn advice submitted with respect to product safety or efficacy. Only when a product approval would compromise significant Health Canada policies would the Minister or his delegate be authorized to override such approval recommendations.

7. Safety and Quality

Under the proposed regulatory framework, all NHPs sold in or into Canada would be obliged to meet certain minimum standards for safety and quality. Consumers must be able to trust that a bottle or package in fact contains the product it claims to contain, and that the product was manufactured according to acceptable standards.

Although the hallmark of an overwhelming proportion of NHPs is their intrinsic level of safety, the regulatory framework must recognize and control the factors that make the use of certain products less safe. "Quality" is one such factor and can be expressed in terms of product identity and purity. Insofar as it also refers to good manufacturing practices, quality is strongly linked to the concept of "safety." Because NHPs are found in nature, the mechanics of processing them and bringing them to market may require many steps, involving many handlers. The purity and cleanliness of the product may be compromised at any step. Generally, Good Manufacturing Practices are designed to prevent poor quality products from reaching the market.

The Advisory Panel believes that the proposed regulatory framework addresses these safety issues in a number of ways. Specifically, the framework includes measures to require:

- Good Manufacturing Practices (GMPs) relevant to NHPs;
- establishment licensing;
- complete product information;
- the intervention and advice of a skilled practitioner, where appropriate.

These elements of the framework are detailed in Section 12, below.

7.1 Safety Categories

The Advisory Panel believes that most natural health products may be described by the term **higher safety. Such products may be safely consumed without the intervention of a professional, provided the consumer is adequately informed though appropriate labels or other forms of product information.**

Certain products, however, would be categorized as lower safety because they are associated with several or all of the following factors:

- **individualized instructions and/or direct practitioner supervision or monitoring is required;**
- **there is a narrow margin of safety between the therapeutic dose and toxic dose;**
- **there are potential or known undesirable or severe side effects at normal**

therapeutic dosage levels;

- **known experimental data has shown that the product induces toxicity in animals but the product has not been in clinical use long enough to establish the pattern of frequency of long-term toxic effects in humans;**
- **their safe use may mask other ailments(s);**
- **they possess a dependence or abuse potential that is likely to lead to harmful non-therapeutic use;**
- **they possess a low level of safety relative to expected benefits;**
- **they have a therapeutic effect based on recently elucidated pharmacological concepts, the consequence of which has not been established.**

The proposed regulatory framework is based on a risk-management model (see also Section 9). Because the safety of a product is a key element in assessing the risk posed by its consumption, the safety categories described above would be used to determine how a product would be processed within the framework.

7.2 Combination Products

Combinations of recognized higher-safety health products would fall under the regulatory guidelines for higher-safety products. Combinations of higher-safety and lower-safety products would fall under the guidelines for the lower-safety products. Traditional and cultural practices must be recognized.

8. Health claims

Once the safety and quality of a natural health product has been assured, the regulatory process may focus on health benefits claimed for the product.

Within the *Food and Drugs Act* and associated regulations, the term "claim" currently has no formal definition in relation to health benefits.

Even so, because of the overwhelming consumer interest in NHPs and their possible applications, the Panel believed it was essential to explore the relationship between claims, product information and consumer understanding.

In general, claims may be defined as statements by NHP manufacturers or distributors regarding the effect of the product on human health.

The Panel has adopted definitions for three major types of claims for natural health products. These are:

- **Structure-function claims**, which report the effect of a product on a structure or physiological function in the human body, and are based on the maintenance or promotion of good health. For example, calcium builds strong bones.

- **Risk-reduction claims**, which relate consumption of a product to significant reduction in the risk of developing a disease or abnormal physiological state. Risk reduction works in two possible ways: One, the product may alter a recognized major risk factor or factors of a disease or abnormal state; or two, it may affect a body function or system so as to improve the body's capacity to resist the disease or abnormal state. For example, garlic decreases the risk of cardiovascular disease.

- **Treatment claims** report the effects of a product on the actions of a specific disease or its symptoms. Treatment can include the cure or alleviation of either the disease or its symptoms. For example, St. John's Wort is useful in the treatment of mild to moderate depression.

8.1 Restrictions on Claims

Ordinarily, such claims would be displayed on the product label, or in associated literature. However, claiming health effects for natural health products is highly problematic under existing *Food and Drugs Act* legislation, for the following reasons:

- Under the regulations written for **foods**, products are not permitted to bear claims of health benefits. Thus, although products such as oat bran, cranberry juice and broccoli are widely perceived as conferring positive health effects, such information may not be carried on the product packaging.

The Advisory Panel believes that existing food regulations ought not to apply to NHPs, principally because of the restrictions on health claims. If consumers are to make informed choices, they need to know which products to use and under what circumstances.

- Under the **drug** regulations, any health benefit must be supported to the satisfaction of conventional medical reviewers. In general, acceptable proof for such claims includes in-depth laboratory research and elaborate clinical trials.

The Panel felt that current drug regulations are too onerous and inappropriate for the control of NHPs, for several reasons:

- Because of the inherent safety of natural health products, it is unnecessarily burdensome to subject them to the rigours of double-blind clinical studies. In other words, the burden of evidence required for pharmaceuticals is excessive and unjustified if applied to NHPs.

- The drug registration process is lengthy and therefore. However, because products

found in nature can generally not be patented, there is usually little potential to recover the costs incurred by the approvals process.

- Pharmaceutical testing, by its nature, seeks to isolate and measure the effect of a particular active substance (usually a single, human-made molecule) on a specific body part or function. This process is inimical to the holistic and energetic principles underlying the use of natural health products.

- NHPs are known substances with long periods of traditional use.

- Schedule A of the Food and Drugs Act, and related provisions, require an interpretation of treatable conditions that is too restrictive for NHPs. (See Section 12 for details).

8.2 No Claims

There was no consensus on the question of whether NHPs could be marketed without health claims.

It was universally agreed that explicit product claims are desirable; there was disagreement, however, over whether they should be mandatory.

A minority held that since NHPs are, under the proposed definition, "therapeutic products," the consumer needs to know what therapeutic effects to expect.

A strong majority, however, argued in favour of permitting NHPs to carry no explicit claims, on the following grounds:

- Some products have so many potential effects that listing them on a label will invariably mean excluding some possible health benefits. This can result in a misinformed public.

- Current law permits therapeutic products to be sold without label claims. Therefore, it is illogical not to retain this option for NHPs.

- Because some claims may have to be proven, the costs of mandatory label claims may prove prohibitive for some vendors. If a manufacturer cannot meet labelling requirements, its product may not be sold in Canada. The consumer is deprived of a potentially valuable remedy.

- Under the proposed regulatory framework, all products are obliged to meet standards for safety and quality. Even without making claims, this requirement gives consumers a higher calibre of product than they can expect now.

It was further noted that a policy to make claims voluntary will at least be necessary during

an interim period while a backlog of existing products pass through the initial licensing process. The Panel also called for an enforcement mechanism to protect against product displays that imply false or unsubstantiated claims.

9. Risk Management

Because the vast majority of NHPs are inherently safe, the focus of regulation should be on those that are less safe – either by their nature, in the way they are produced, or in the way they are used. Thus, the framework is founded on a risk-management model, which seeks to identify, contain and ultimately reduce the risk of using natural health products.

In general, the Panel made three key findings with respect to risk:

- 1. Regulations must require products to adhere to quality and safety standards that may substantially mitigate risk.
- 2. Products with lower safety margins should be held to higher standards within the regulatory process; and
- 3. Risk assessments for NHPs may refer to a wider variety of reference sources than conventional pharmaceutical drug evaluations.

These considerations are detailed in the sections below.

10. Safety and Quality Assurance

The federal regulator may resort to a variety of mechanisms to ensure that consumer products sold in or into Canada meet certain basic standards of safety and quality. Assurance of these standards is a key factor in mitigating risks associated with consuming any product, including NHPs. (See also Section 7 for an analysis of safety and quality issues.)

This section outlines some of the tools available to the regulatory authority.

10.1 Good Manufacturing Practices

GMPs are standards governing the manufacture and distribution of products. They cover such areas as sanitation, record keeping, quality control and testing of raw materials and finished products. The object of such guidelines is to safeguard the safety and quality of products sold in or into Canada.

At present, there are only voluntary GMPs for foods. The *Food and Drugs Act* outlines mandatory GMPs only for drugs. These are described in Division 2 regulations and related guidelines and annexes.

Moreover, supplementary GMPs were developed in October 1996 for the manufacture of Herbal Medicinal Products. These sought to take into account the variability of geographic origins for plant species made into herbal remedies, as well as the chemical and biological complexity of the active ingredients.

The Advisory Panel believes that GMPs and processing standards must be carefully reviewed in light of the particular characteristics of NHPs. The standards to be developed must simultaneously reflect the uniqueness of the product, safeguard public safety, and place no unnecessary burden on the NHP industry.

10.2 Establishment Licensing

The Advisory Panel supports the concept that all manufacturers, packagers, importers and distributors selling NHPs to Canadians in Canada should hold a valid establishment licence. The issuance of such a licence is contingent on compliance with GMP requirements; maintenance of the licence depends on continued GMP compliance. Licensed establishments are subject to inspection by the regulatory authority.

Only firms holding a valid establishment licence would be permitted to handle or market licensed natural health products.

The licensing process would include an open, transparent and speedy appeals mechanism.

10.3 Product Information

Because many NHPs are intended for self-medication, the attendant risks may be strongly reduced or eliminated by means of suitable consumer information.

Thus, the product label, packaging, insert or other forms of information must comprise at minimum the following information:

- The identity of the product, which normally includes its name and composition;

- Directions for use;
- Any cautions, warnings or restrictions on the use of the product;
- A lot or batch number to allow for GMP controls and to facilitate recalls
- An expiry date to guide consumers on the expected shelf live under specified storage conditions;
- Special storage conditions, if any.

In addition, subject to regulatory approval, the label may also make claims of health benefits or effects. For a detailed discussion on the regulatory process guiding product assessment and validation of claims, please see Section 11.)

10.4 Professional Intervention[1]

Without limiting the requirement for informative consumer information for NHPs, the Advisory Panel also acknowledges the key role played by natural health care practitioners.

Some products, such as formulations, compounds and special herbal essences, are crucial to the practice of particular types of care, and are therefore typically only prepared by and available through the attending practitioner or other appropriately trained persons.

Other products may be generally available, but are more safely or effectively used under the care of a complementary or natural health-care specialist.

The Panel believes this proposed regulatory framework, founded on the management of risk, must take full advantage of the expertise of professionals. For example, the regulations may specify that products of lower safety may only be available under the care of a practitioner.

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[1] A qualified practitioner is one who has received training in a particular discipline and is held by a group of peers to be properly qualified to practise that discipline. Appropriate expertise includes, but is not limited to, holistic nutrition, orthomolecular medicine, Western herbal medicine, homeopathy, Native American, traditional Chinese or Ayurvedic medicine, and any culturally based system that is well represented among the Canadian populace.

At the same time, however, the Panel was conscious of the difficulty of recommending a formalized structure involving practitioners at a time when the practitioners themselves are not generally regulated in most provinces.

Therefore, the Panel also recommended that the federal government urge the provinces to examine the issues surrounding the licensing of complementary health-care practitioners.

Until practitioners are adequately regulated by the provinces, all low safety natural health products be allowed for sale as long as the label includes the following:

(1) A statement that the product has been classified as low-safety by the regulatory body.

(2) A statement of the nature of the risks associated with the use of the product, including all counter-indications, etc..

(3) A statement that the consumer should consult with a qualified practitioner before using.

11. Product Licensing

Within the risk-management framework outlined in Section 9 above, NHPs may be licensed for sale in or into Canada. The Advisory Panel concluded that the licensing process should take two forms: post-market notification, and pre-market submission for review.

Simply put, the distinction between the two regulatory channels lies in the amount of available knowledge accepted in understanding and limiting potential risks, and in supporting any health benefit claims.

Licensing decisions would be published. They would also be subject to review under an open, transparent and independent appeals process.

11.1 Post-market Notification

For marketing purposes, where pertinent and appropriate monographs and standards exist, manufacturers, importers and distributors of higher safety products would be required to notify the government within 30 days of placing the product on the Canadian market: . The standardized notification form would include but not be limited to the following information:

- **product name and composition**
- **License number (establishments must hold a License and meet yet to be established Good Manufacturing Practices {GMP} standards to ensure the safety and quality of the product)**
- **attestation to a monograph or standard recognized by the Canadian Regulatory Authority**

The Natural Health Products regulatory body would issue a confirmation or acknowledgment of notification.

It is important to recognize that there are few current Canadian standards for NHPs and that there needs to be an immediate effort to create and accept standards for these products. The Panel recommends that government not spend unnecessary effort to create special standards where such exist elsewhere and are readily accessible and reviewable. Recognition of traditional and cultural standards would be essential to the ongoing development of this system.

11.2 Pre-market Submission for Review

Products that do not meet the requirements under Section 11.1 above would be ineligible for marketing under a post-market notification. These products would need to be reviewed by the regulatory authority before they could be sold in Canada.

Specifically manufacturers, importers and distributors of new products for which there are no recognized monograph or standards, or where the product, is classified as a lower safety product, would be required to submit evidence for review to the Natural Health Products regulatory body prior to placing their products onto the Canadian market. The standardized submission form would include but not be limited to the following information:

- product name and composition
- License number (establishments must hold a License and meet yet to be established Good Manufacturing Practices {GMP} standards to ensure the safety and quality of the product)
- traditional and cultural references, published literature, clinical evidence (including, but not limited to controlled clinical trials) and professional consensus by appropriate, recognized practitioner groups.

The Natural Health Products regulatory body would issue certification, or other form of Product Licence, which would include labeling requirements such as indications for use, warnings, precautions and access restrictions, prior to marketing by the manufacturers and distributors.

11.3 Standards of Evidence for Claims

The regulator would also assess the validity and credibility of the sources of data submitted for review. Unlike pharmaceutical reviews, which depend heavily on clinical trials, the Panel believes that a broader range of supporting evidence should be acceptable for natural health products.

Where double-blind clinical studies, the gold standard for pharmaceutical evaluations, are available, these should certainly be accepted as part of the review submission. Similarly, product monographs and published standards should be viewed as credible sources of supporting data.

However, the Advisory Panel believes the following sources, whether found in Canada or abroad, must also be considered for acceptance, provided they have been approved by the expert advisory groups of the regulatory authority:

- traditional or culturally based[2] references, which are often based on many years – indeed, centuries – of product experience;
- published literature other than mainstream scientific journals;
- clinical evidence, including, but not limited to, controlled, double-blind, multi-centre trials.
- professional consensus, as accepted by subject matter experts.

12. Outdated Legislation

The Advisory Panel recommends that outdated legislative restrictions in the *Food and Drugs Act* be rescinded and the Traditional Herbal Medicine Policy be replaced by a new policy.

The Panel expressed grave concern about the existence of Schedule A of the *Food and Drugs Act*, and recommend its immediate rescindment.

Enacted in 1934, Schedule A lists a number of diseases, disorders and abnormal physical states – from asthma and cancer to dysentery and gangrene – for which treatments, preventatives or cures cannot be advertised or sold to the general public. The purpose of the Schedule and related sections of the Act are to prevent fraud and to encourage people to seek medical attention for serious conditions.

However, the Panel felt the provisions are outdated. Worse, at a time when consumers are demanding greater choice in health care, Schedule A poses a needless and onerous restriction.

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[2] A culturally based medical paradigm is one practised by various cultures. These include, but are not limited to: traditional Chinese, Ayurvedic, Western herbal and Native North American forms of medicine. Recognition of these paradigms includes recognition of their related references, texts and models.

Indeed, the Panel said the provisions contravene the core purpose and objectives of the regulatory framework for NHPs, and should urgently be rescinded.

Another such restriction is the outright prohibition of sampling to consumers regardless of safety. Other consumer goods with lower safety profiles are permitted to be sampled to consumers under appropriate regulatory controls. Higher safety products should be permitted greater marketing freedom than lower safety products. This can be accomplished through a regulation rather than a legislated prohibition.

13. Other Considerations

Several issues of great importance were reviewed by the panel which impact on the future of this category of products.

Bulk Herbs: Although bulk herbs do not fit within the definition of NHPs because they are not sold in dosage form, the Panel was concerned that bulk herbs may currently be available on the Canadian market without adequate standards of quality, identity or purity. The Panel also recognizes that any policy and process developed by a regulatory authority must be cognizant of traditional and culturally-based practices.

Grandfather Clause and Interim Measures: Panel members were agreed that existing products already on the market must be managed in a fair manner once the new regulatory framework is in place. Similarly, they believed that a phase-in period is necessary to allow manufacturers, importers and distributors to bring their processes and procedures in line with the new regulations.

Genetically Altered DNA: The Panel agreed that any NHP containing substances with genetically altered DNA must be clearly labelled as such.

Research: Because NHPs and their active components cannot be patented, Panel members felt that the federal government should provide incentives to research new claims for NHPs.

14. Stakeholder and Consumer Involvement

Because the proposed regulatory framework is intended to be viewed as a unified whole, the Advisory Panel was concerned about the possibility of misinterpretation, fragmentation or selective implementation of the recommendations. Therefore, the Panel recommends that the proposed framework be considered in its entirety.

Moreover, the Panel calls on legislators to involve representatives of the NHP industry and practitioners of complementary medicines and consumers as significant co-authors and equal participants in drafting the new regulations.

And finally, the Panel recommends that the new framework, when implemented, be subjected to periodic review, to ensure it continues to deliver on its original intent. This would include a regular assessment of the performance and effectiveness of the regulatory authority.

Summary and Conclusions

The Advisory Panel on Natural Health Products believes that a fair and effective regulatory process can and must be devised for Natural Health Products.

The principal objective of such a framework is to meet consumer demand for free access and choice in their personal health care, in a way that protects them from misinformation, unsafe products or fraud.

The framework presupposes that the natural health products industry has an obligation to supply the Canadian market with high quality products that meet certain minimum safety standards. The consumer, meanwhile, is responsible for informed and intelligent use of products that, while generally very safe, are nevertheless plainly intended as medications.

In this context, the role of the government regulator is to level the competitive playing field, allowing the industry to fulfil its obligations to the consumer, and the consumer to make free and informed decisions.

Thus, the proposed framework tends more toward the permissive than the prescriptive, its interventions minimalist unless potential risks to the public warrant greater intrusion by the state.

Given the delicacy of the balances that must be struck, and the inherent complexity of the issues, the Panel took nearly a full year to reach the consensus positions described in this report. For the same reasons, the Panel urges the drafters of a new regulatory framework to tread with caution, and only after a thorough exploration of the issues involved.

Central to that exploration will be continued consultation with people experienced in the field, stakeholders, consumers, producers and practitioners, who know and appreciate natural health products.

In that context, the Panel acknowledges the efforts made by the Therapeutic Products Program of Health Canada and the House of Commons Standing Committee on Health to solicit the counsel of the Advisory Committee and others in framing a new set of controls for NHPs.

The Panel members sincerely hope that stakeholder consultations will not end with the enactment of a new regulatory framework. Indeed, they request that they be permitted to remain involved with the deliberations to ensue.

Annex A

Key Recommendations

The Advisory Panel on Natural Health Products recommends that:

- the concepts and definitions contained in the *Food and Drugs Act* be restructured to permit the creation of a third category of products – specifically, natural health products – and that these NHPs be defined as "substances or combinations of substances consisting of molecules and elements found in nature, and homeopathic preparations, sold in dosage form for the purpose of maintaining or improving health and treating or preventing diseases/conditions";

- Schedule A and related provisions of the *Food and Drugs Act* be immediately rescinded on the grounds that they contravene the core objectives of the proposed regulatory framework for NHPs;

- representatives of the NHP industry and practitioners of complementary medicines and consumers be involved in drafting the new regulations;

- the proposed regulatory framework;

    - be viewed as a unified whole;

    - respect the unique character of NHPs;

- uphold the consumer's right free choice and access to safe, high-quality, clearly labelled NHPs;
- be founded on a risk-management model that would identify and mitigate hazards to the Canadian public, while permitting the speedy marketing of demonstrably safe and high-quality products;
- be cost-effective, minimalist in scope, independent, and guided by the expertise of individuals skilled in the field of natural health care;
- include an open, transparent, speedy and independent appeals process;
- be subjected to a periodic review of its performance and effectiveness;

➢ manufacturers, packagers, importers and distributors of natural health products, whether located in Canada or abroad, be obliged to hold valid establishment licences, which attest to continued compliance with Good Manufacturing Practice standards specific to NHPs;

➢ products meeting specific tests for safety, quality and attestation to recognized monographs, standards or traditional and cultural references be permitted on the Canadian market with only a requirement to notify the regulatory authority;

➢ products subjected to regulatory review be evaluated to an extent commensurate with their potential risk;

➢ risk assessments be made in light of a broader range of reference sources than conventional drug evaluations;

- product labels be complete, accurate and informative;
- the federal government urge the provinces to examine the issues surrounding the licensing of complementary health-care practitioners;

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